

of that microorganism. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§ 866.2500 Microtiter diluting and dispensing device.

(a) *Identification*. A microtiter diluting and dispensing device is a mechanical device intended for medical purposes to dispense or serially dilute very small quantities of biological or chemical reagents for use in various diagnostic procedures.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§ 866.2540 Microbiological incubator.

(a) *Identification*. A microbiological incubator is a device with various chambers or water-filled compartments in which controlled environmental conditions, particularly temperature, are maintained. It is intended for medical purposes to cultivate microorganisms and aid in the diagnosis of disease.

(b) *Classification*. Class I (general controls). This device is exempt from premarket notification procedures in subpart E of part 807. The device also is exempt from the good manufacturing practice regulation in part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 866.2560 Microbial growth monitor.

(a) *Identification*. A microbial growth monitor is a device intended for medical purposes that measures the concentration of bacteria suspended in a liquid medium by measuring changes in light scattering properties, optical density, electrical impedance, or by making direct bacterial counts. The

device aids in the diagnosis of disease caused by pathogenic microorganisms.

(b) *Classification*. Class I. With the exception of automated blood culturing system devices that are used in testing for bacteria, fungi, and other microorganisms in blood and other normally sterile body fluids, this device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 60 FR 38482, July 27, 1995]

§ 866.2580 Gas-generating device.

(a) *Identification*. A gas-generating device is a device intended for medical purposes that produces predetermined amounts of selected gases to be used in a closed chamber in order to establish suitable atmospheric conditions for cultivation of microorganisms with special atmospheric requirements. The device aids in the diagnosis of disease.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§ 866.2600 Wood's fluorescent lamp.

(a) *Identification*. A Wood's fluorescent lamp is a device intended for medical purposes to detect fluorescent materials (e.g., fluorescein pigment produced by certain microorganisms) as an aid in the identification of these microorganisms. The device aids in the diagnosis of disease.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the good manufacturing practice regulation in part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

§ 866.2660 Microorganism differentiation and identification device.

(a) *Identification*. A microorganism differentiation and identification device is a device intended for medical purposes that consists of one or more